



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,840	10/30/2003	David W. Wynn	MCP-5021	9284
27777	7590	02/20/2008	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			GEORGE, KONATA M	
		ART UNIT		PAPER NUMBER
		1616		
		MAIL DATE	DELIVERY MODE	
		02/20/2008	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/697,840	WYNN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	KONATA M. GEORGE	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20 November 2007.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,3-6,9-15,17-21 and 24-26 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 1,3-5,9-13,15 and 17 is/are allowed.
- 6) Claim(s) 6,14,20 and 21 is/are rejected.
- 7) Claim(s) 24-26 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 29 March 2004 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

Claims 1, 3-6, 9-15, 17-21 and 24-26 are pending in this application.

***Action Summary***

The examiner acknowledges the cancellation of claims 2, 8, 18, 19, 22 and 23. Therefore, any and all objections and/or rejections directed to them are hereby withdrawn.

**The rejection of claims 6, 20 and 21 under 35 U.S.C. 112, second paragraph, as being indefinite is being maintained for the reasons stated in the office action dated August 8, 2007.**

***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6, 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants use the phrase "less than about" or "greater than about" in the claims when describing the dry weight of the coating. It is unclear to the examiner if it is "less than", "greater than" or "about" that are being claimed.

***Response to Arguments***

Applicant has submitted a response to this rejection; therefore, it is being maintained.

**The rejection of claim 14 under 35 U.S.C. 112, second paragraph, as being indefinite is being maintained for the reasons stated in the office action dated August 8, 2007.**

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants in the claims recite the phrase "derivatives". Webster's Dictionary defines a derivative as "a substance derived from, or of such composition and properties, that it may be considered as derived from, another substance by chemical change, esp. by the substitution of one or more elements or radicals". Based on this definition it is unclear what the derivative is.

***Response to Arguments***

Applicant has submitted a response to this rejection; therefore, it is being maintained.

**The rejection of claims 1, 3-6, 9-15, 17-21 and 24-26 under 35 U.S.C. 103(a), as being unpatentable over Ratnaraj et al. in view of Singh et al. and Robinson et al. is hereby withdrawn in view of applicant arguments that the combination of**

**references do not teach the particles are not covered with a controlled release layer comprising an insoluble film-forming polymer and an enteric polymer.**

***Claim Objections***

Claims 24-26 are objected to because of the following informalities: These claims depend upon a cancelled claim, which is improper. Appropriate correction is required.

***Allowable Subject Matter***

Claims 1, 3-5, 9-13, 15 and 17-19 are allowed. The prior art does not teach, suggest or make obvious a pharmaceutical composition comprising particles of NSAID and/or acetaminophen which is coated with a controlled release layer composition comprising an insoluble film-forming polymer and an enteric polymer. The closest prior art reference Robinson et al. teaches coating a particles with a combination of two or more film-forming polymers, Robinson et al. do not teach or suggest using enteric coating in the coating layer.

***Conclusion***

Claims 6, 14, 20 and 21 are rejected,

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1616

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Art Unit: 1616

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konata M. George  
Patent Examiner  
Art Unit 1616



Johann R. Richter  
Supervisory Patent Examiner  
Art Unit 1616